

Application No.: 09/700,625

Attorney Docket No.: DALHO1290-1

Filing Date: February 1, 2001

(028614-1102)

Response to Office Action (mailed July 20, 2004) faxed October 13, 2004

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Remarks

The present invention provides compositions containing specifically defined second or third generation antidepressants, formulated for local or topical administration. Invention compositions have been shown to produce local analgesia in subjects having a site of local discomfort. Invention formulations possess the advantage of providing a higher and more efficacious concentration of active agent to the region of the sensory nerve terminal than is achievable with systemic administration of the same active agent. In addition, invention compositions for local or topical administration greatly reduce the side effects that may result from systemic administration of antidepressants.

Claims 37-44, 49-53 and 73-83 were pending in the present application prior to the present communication. By this communication, claims 44, 49-52, 75 and 80 have been amended to define Applicants' invention with greater particularity. These amendments add no new matter as they are fully supported by the specification and original claims. In addition, by the present communication, claims 37-43, 73, 79 and 81 have been cancelled without prejudice. The amendments submitted herewith are respectfully submitted to place the present application in condition for allowance, or at a minimum, in better condition for appeal. Moreover, the number of claims under consideration has been substantially reduced by the amendments submitted herewith. Accordingly, entry of the amendments submitted herewith is respectfully requested.

In view of the amendments submitted herewith, claims 44, 49-53, 74-78, 80 and 82-83 remain pending. The present status of all claims in the application is provided in the Listing of Claims presented herein beginning on page 2.

The rejection of claims 37-41, 73 and 79-83 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because of alleged new matter, is respectfully traversed for the reasons set forth in Applicants' prior communications. However, in order to reduce the issues and expedite prosecution, claims 37-41, 73, 79 and 81 have been cancelled, without prejudice. Thus, of the claims subject to this rejection, only claims

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80 and 82 remain pending, and they have each been amended to remove the objected to language.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 37-41, 73 and 79-83 under 35 U.S.C. § 112, first paragraph.

The provisional rejection¹ of claims 37-43, 73, 74, 76, 79 and 81 under 35 U.S.C. § 102(b), as allegedly being anticipated by Amer, U.S. Patent No. 5,266,571 (hereinafter referred to as "571"), is respectfully traversed. To the extent this provisional rejection is directed to claims 37-43, 73, 79 and 81, the rejection has been rendered moot by the cancellation of these claims by the present communication.

With respect to remaining claims 74 and 76, this rejection is submitted to be in error. Claim 74, for example, defines the present invention in very specific terms, requiring the second or third generation antidepressant to be selected from a limited list of compounds. This presentation is fully consistent with the Examiner's suggestion at page 2, lines 15-16 of the Office Action, that "applicants list the desired compounds in a markush format."

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 37-43, 73, 74, 76, 79 and 81 under 35 U.S.C. § 102(b).

The provisional rejection² of claims 75, 77, 78, 80, 82 and 83 under 35 U.S.C. § 103(a), as allegedly being unpatentable over '571 in view of Knepp *et al.*, *J. Controlled Release* 12:25-30, 1990 (hereinafter referred to as "Knepp"), is respectfully traversed. Applicants' invention, as defined, for example, by claim 75, distinguishes over the cited references by requiring a composition for topical administration comprising a second or third generation antidepressant selected from a limited list of compounds, wherein said composition further comprises a

¹ Provisional rejection set forth at the bottom of page 3 of the Office Action, contingent on resolution of the rejection under 35 U.S.C § 112, first paragraph, addressed above.

² Provisional rejection set forth at the top of page 4 of the Office Action, contingent on resolution of the rejection under 35 U.S.C § 112, first paragraph, addressed above.

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penetration enhancing agent. Neither of the applied references disclose or suggest the claimed compositions.

As noted above, '571 does not anticipate the present invention. Further reliance on the secondary reference, Knepp, is unable to cure the deficiencies of '571. Indeed, it is respectfully submitted that Knepp is not relevant to the present claims as the reference is merely directed to a specific delivery system. No motivation exists, absent Applicants' disclosure, to combine the asserted references. Such use of Applicants' disclosure is improper.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 75, 77, 78, 82 and 83 under 35 U.S.C. § 103(a).

It is respectfully submitted that Applicants have addressed all issues of record. Note that claims 44 and 49-53 were not subject to any rejections, only objected to as dependent from a rejected base claim. By re-writing each of these claims in independent form, each is respectfully submitted to be in condition for allowance.

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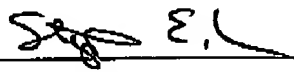
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Conclusion

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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